UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES – GENERAL

Case No. CV 17-3178-CAS (KSx); CV 17-3196-CAS (KSx) Date: September 12, 2018

Title *John Bower v. Wright Medical Technology; Catherine Prater v. Wright Medical Tech.*

Present: The Honorable: KAREN L. STEVENSON, United States Magistrate Judge

G. Roberson	N/A
Deputy Clerk	Court Reporter / Recorder

Attorneys Present for Plaintiffs: Attorneys Present for Respondent:

Proceedings: (IN CHAMBERS) ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFFS' MOTION TO COMPEL FURTHER DISCOVERY RESPONSES AND PRODUCTION OF DOCUMENTS (Dkt. No. 60)

Before the Court for decision is Plaintiff's Motion to Compel Further Discovery Responses and Production of Documents ("Motion to Compel".) (Dkt. No. 60.) The parties filed the Motion to Compel on July 25, 2018 in the Joint Stipulation format pursuant to Local Rule 37-2 ("Joint Stip."), following a telephonic conference with the Court. (*See* Dkt. No. 56.) On August 8, 2018, Plaintiff filed a Supplemental Memorandum in Support of the Motion to Compel. (Dkt. No. 68.) On August 22, 2018, the Court heard oral argument on the Motion to Compel. (Dkt. No. 74.) At the hearing, the Court determined that it needed additional information from the parties concerning Plaintiffs' request for evidence related to Defendants' communications with the Food and Drug Administration ("FDA") regarding fracture incidents involving Defendants' titanium 1254 long neck hip implant product for the period 1999 through 2017. (*Id.*) The Court scheduled a further telephonic conference on this issue for September 7, 2018. (*Id.*)

On September 7, 2018, the Court heard further argument from the parties regarding the remaining issue in dispute and took the matter under submission. (Dkt. No. 79.) The matter is now fully briefed and ready for decision.

For the reasons discussed below, the Motion is GRANTED in part and DENIED in part.

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FACTUAL BACKGROUND

This action consolidates two lawsuits filed by plaintiffs John Bower and Catherine Wright (together, "Plaintiffs").[1] Plaintiffs each had hip replacement surgery in which they received the PROFEMUR® Total Hip System, composed of cobalt-chromium (CoCr) alloy (Product No. PHAC-1254) (the "Cobalt Chrome Device") manufactured, marketed, and sold by Defendant. (Joint Stip. at 1-2.) The operative complaints allege that due to design defects, the PROFEMUR® devices suddenly fractured at the "Neck-Stem-body transition" causing Plaintiffs to endure unnecessary pain and subsequent revision surgery to replace the failed devices. (*Bower* First Amended Complaint ("FAC") ¶¶ 1-2; *Prater* Complaint ¶¶ 1-2.)

Plaintiffs allege that "Defendants have known for several years that their hip replacement device – the PROFEMUR® Total Hip System with the PROFEMUR® Stem and PROFEMUR® Neck — was prone to fail within a few years of implantation . . . [and that] Defendants have long known that their Device has a tendency to fracture at the location of the highest tensile stress concentration in the Neck-Stem-body transition during even low to moderate physical activity." (*Prater* Complaint ¶ 1; *Bower* FAC ¶ 1.)

Plaintiffs allege that "[t]he Wright Medical PROFEMUR® modular necks that were distributed after December 13, 2000 and before August 25, 2009, were all made of a titanium-aluminum-vanadium alloy known as Ti6A14V" (the "Titanium Device"). (*Prater* Complaint ¶ 21; *Bower* FAC ¶ 21.) Starting in August 2009, Wright distributed and marketed the PROFEMUR® device manufactured from cobalt chrome alloy instead of Ti6A14V and represented to the FDA that the Cobalt Chrome Device was "substantially equivalent" to the Titanium Device. (*Prater* Complaint ¶ 22; *Bower* FAC ¶ 22.) According to Plaintiffs, the PROFEMUR® modular necks that were promoted, marketed, distributed, and sold in the United States after December 13 2000, were manufactured in twelve different model styles, including

[1] Separate, but similar products liability actions were previously filed and consolidated in this district by Richard Sarafian, *Sarafian v. Wright Medical Technology, Inc. et al.* Case No. CV 15-09397-CAS (KSx); and Kristin Biorn, *Biorn v. Wright Medical Technology, Inc. et al;* CV 15-07102-CAS (KS) against Defendants also alleging defects in the Cobalt Chrome Device), (together the "*Biorn/Sarafian* Actions"). The *Biorn and Sarafian* Actions have now been resolved.

six that Wright identified as "short" necks and six Wright identified as "long" necks. (*Prater* Complaint ¶ 23; *Bower* FAC ¶ 23.)[2] Plaintiffs alleged that prior to 2001, Wright "had received notice of clinical failures in the form of fractures of modular necks that had been implanted in patients in Europe." (*Prater* Complaint ¶ 28; Bower FAC 28.)

Prater underwent a right total hip replacement on January 17, 2012 and the long neck Cobalt Chrome Device that she received failed on January 9, 2017, requiring revision surgery. (*Prater* Complaint ¶ 3.) Bower underwent a left total hip replacement on October 1, 2013 and the Cobalt Chrome Device he received failed on December 4, 2016, necessitating revision surgery. (*Bower* FAC ¶ 3.)[3] On August 11, 2015, Defendant MicroPort announced a voluntary recall of the Cobalt Chrome long neck model PHAC-1254, the device that was implanted into Plaintiffs. (*Prater* Complaint ¶ 60; *Bower* FAC ¶ 60.)

Plaintiffs alleged that the Cobalt Chrome Device that they were implanted with was "unreasonably dangerous due to design flaws that caused excessive micromotion and fretting corrosion which increased the potential for failure. (*See Pater* Complaint ¶ 74; *Bower* FAC ¶ 74.) Plaintiffs each assert causes of action for: (1) strict products liability – manufacturing defect; (2) strict products liability – failure to warn; (3) negligence; (4) negligence – failure to recall; (5) fraudulent misrepresentation; (6) fraudulent concealment; and (7) negligence misrepresentation. (*Prater* Complaint ¶¶ 93-144; *Bower* FAC ¶¶ 93-145.)

THE MOTION

In the Motion, Plaintiffs seek to compel Defendants to produce additional documents relating to the following five disputed issues:

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[2] The "short" neck titanium products were identified by Catalog #s PHA0-1202, PHA0-1212, PHA0-1232, PHA0-1242,.and PHA0-1252, while the "long" neck titanium products were identified by Catalog #s PHA0-1204, PHA0-1214, PHA0-1224, PHA0-1234, PHA0-1244, and PHAO-1254. (*Prater* Complaint ¶ 23; *Bower* FAC ¶ 23.)

[3] At the time of Plaintiffs' revision surgeries, the Cobalt Chrome Device that they each received was manufactured, labeled, marketed, promoted, and distributed by Defendant MicroPort Orthopedics, Inc. (*Bower* FAC ¶3; *Prater* Complaint ¶ 3.) In 2014, MicroPort acquired Wright Medical Technology Inc.'s OrthoRecon Division, which was the hip division that designed and sold the PROFEMUR® modular necks implanted in Plaintiffs. (*Prater* Complaint ¶ 59; *Bower* FAC ¶ 59.)

- **Issue # 1:** Documents related to fractures in the entire PROFEMUR® product line, including individual complaint files concerning all other CoCr neck fractures, including other CoCr long neck fractures, not just the PHAC-1254 component implanted in Plaintiffs (Joint Stip. at 41-43);

- **Issue # 2:** Documents concerning PROFEMUR® TITANIUM LONG NECK implant device (Product No. PHAO-1254) (the "Titanium Device") (Joint Stip. at 61-65) ;

- **Issue # 3:** Documents evidencing failures in PROFEMUR® CoCr devices, including evidence of corrosion present in any PROFEMUR® neck component, including long, short, and titanium models, including evidence related to adverse tissue reactions (Joint Stip. at 80- 83);

- **Issue # 4:** Documents relating to the failure rate of the PROFEMUR® neck line of products, including titanium and CoCr necks, without limitation by time or specific model (Joint Stip. at 114-116); and

- **Issue # 5:** Communications with the FCA regarding the PROFEMUR® line, including individual complaint files relating to titanium neck fracture incidents (Joint Stip. at 123-124).

Because Plaintiffs' individual discovery requests pertaining to each of the issues identified above are voluminous, the Court has not recited the requests and Defendants' objections in the body of this Order. Rather, Plaintiffs' Document Demands and Defendants' Responses corresponding to each issue, as outlined in the parties' Joint Stipulation, are attached hereto as Appendices 1 through 5, respectively.

LEGAL STANDARD

Under Rule 26 of the Federal Rules of Civil Procedure, a party may obtain discovery concerning any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case. FED. R. CIV. P. 26(b)(1). As amended in December 2015,

Rule 26(b)(1) identifies six factors to be considered when determining if the proportionality requirement has been met, namely, the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to the relevant information, the parties' resources, the importance of the discovery in resolving the issues and whether the burden or expense of the proposed discovery outweighs its likely benefit. (*Id.*) Relevant information need not be admissible to be discoverable. (*Id.*)

District courts have broad discretion in controlling discovery. *See Hallett v. Morgan*, 296 F.3d 732, 751 (9th Cir. 2002). When considering a motion to compel, the Court has similarly broad discretion in determining relevancy for discovery purposes. *Surfvivor Media, Inc. v. Survivor Productions*, 406 F.3d 625, 635 (9th Cir. 2005) (citing *Hallet*, 296 F.3d at 751).

DISCUSSION

Issue No. 1: Documents Related to Fracture Incidents in the Entire PROFEMUR® Cobalt Chrome Product Line

Plaintiffs argue that Defendants only produced Plaintiffs' individual complaint reports for the fractures they suffered but did not produce reports and documents concerning all other CoCr neck fractures, including other CoCr long neck fractures. (Joint Stip. at 41.) Plaintiffs maintain that documents related to products not implanted in Plaintiffs are relevant to prove Plaintiff's failure to warn causes of action. (*Id.*) Further, Plaintiffs contend that they are entitled to discovery concerning the entire PROFEMUR® CoCr product line, not just the specific component (PHAC-1254) implanted in Plaintiffs because the "modular design of the PROFEMUR® line is central to Plaintiffs' claims, and there is no dispute that all PROFEMUR® necks are identical at the oval taper junction, the very location where Plaintiffs' CoCr long necks fractured." (*Id.* at 43.)

Defendants, not surprisingly, respond that discovery of other fracture complaints involving the PROFEMUR® CoCr neck is not relevant to Plaintiffs' claims because "every modular neck failure, whether fracture-related or not has distinguishing features" with respect to "causation, symptomology and patient experiences, among other factors." (Joint Stip. at 45.) Further, Defendants point out that they have already "produced all of the post-market

surveillance reports for the entire PROFEMUR® CoCr product line regardless of failure mode." (Joint Stip. at 46.) In addition, Defendants note that they have also produced design files, regulatory files, marketing materials, testing documents, and post-market surveillance reports previously produced by Defendants in the *Biorn*/*Sarafian* Actions and these documents pertain to the entire PROFEMUR® CoCr product line, not just the PHAC-1254 component. (*Id.*) Defendants also point out that they have previously offered to produce information concerning the one other reported fracture of a non-PHAC-1254 modular neck. (*Id.* at 47.) On this basis, Defendants urged at oral argument that further discovery of other fracture complaints related to the PROFEMUR® CoCr neck product line is not relevant and would not be proportionate to the needs of this case.

Defendants cite a number of cases in support of the proposition that discovery regarding different PROFEMUR® COCr products are not relevant. (*See* Joint Stip. at 45.) These cases, however, do not appear to have been decided in the discovery context. *See, e.g.*, *Hill v. Novartis Pharms. Corp.*, 944 F. Supp. 2d 943, 952-53 (E.D. Cal. 2013) (rulings on motions *in limine* and discussing appropriate scope of opening statement at trial); *Broadcom Corp. v. Emulex Corp.*, Nos. SACV 09–01058–JVS (ANx), CV 10–03963–JVS (ANx), 2011 WL 11025895, at *1-2 (C.D. Cal. Dec. 13, 2011) (order on motion for post-trial relief under Rule 50). Nevertheless, in light of the particular claims and defenses at issue here and Defendants' representations at oral argument concerning the resources, both in time and manpower, that would be needed to examine individual incident files for the entire product line, the Court is not persuaded that discovery concerning the entire PROFEMUR® CoCr product line is relevant or proportionate to the needs of this case. *See* FED. R. CIV. P. 26(b)(1).

During oral argument, Plaintiffs pointed out and Defendants conceded that they have produced portions of the discovery previously produced in the *Biorn/Sarafian* Actions, which also involved individual incidents of fractures in the PROFEMUR® CoCr long neck product. Consequently, because *Biorn/Sarafian* discovery has already been assembled and produced by Defendants in prior litigation involving the same CoCr product # PAC-1254 and Defendants admit that they have produced portions of the *Biorn/Sarafian* discovery in this action, the Court finds no undue burden to Defendants to produce the *Biorn/Sarafian* discovery in its entirety in

this action. (*See Biorn v. Wright Medical Technology et. al/Sarafian v. Wright Medical Technology, Inc. et. al*, CV 17-7102-CAS (KSx) [Dkt. No. 112].)

Accordingly, the Motion to Compel is GRANTED in part and DENIED in part, insofar as any additional discovery concerning the PROFEMUR® CoCr product line beyond the specific product implanted into Plaintiffs will be limited to the discovery previously produced in the *Biorn/Sarafian* Actions.

Issue No. 2: Evidence of Fractures of PROFEMUR® Titanium Necks

As noted above, the PROFEMUR® Titanium Device was a predecessor hip implant product that Wright designed, manufactured, and sold between 1999 and 2009. (*See Prater* Complaint ¶ 21; *Bower* FAC ¶ 21.) Starting in August 2009, Wright distributed and marketed the Cobalt Chrome Device as a substitute for the Titanium Device. (*Prater* Complaint ¶ 22; *Bower* FAC ¶ 22.) In the Motion to Compel, Plaintiffs seek extensive discovery concerning the Titanium Device. (*See* Appendix 2.) Here, too, Plaintiffs argue that information concerning evidence of Titanium Device fractures, including fractures of "short" neck products, is relevant to their defective design and failure to warn causes of action. (Joint Stip. at 61-64.)

Specifically, Plaintiffs maintain that that because Defendant Wright Medical represented to the FDA that the design of the CoCr and titanium necks were "substantially equivalent," the evidence of neck fractures in the titanium device that are similar to the Cobalt Chrome Device failures that Plaintiffs experienced is highly relevant to the issues of notice. (*See* Joint Stip. at 61-62.) Plaintiffs also point to a discovery order issued in the *Biorn/Sarafian* Actions, which concluded that discovery concerning the Titanium Device was "relevant to the claims at issue and proportionate to the needs of [those] cases." (Joint Stip. at 61 (quoting *Biorn/Sarafian* Dkt. No. 112).)

Defendants challenge the relevance of the Titanium Device discovery by pointing to testimony of various experts, including Plaintiffs' expert, who opined that the fracture patterns in the titanium alloy stems and the CoCr devices are not similar and that damage observed in fractured CoCr devices is inconsistent with the types of damage observed in titanium devices. (*See* Joint Stip. at 66.) But as the Court emphasized during oral argument, this "battle of the experts" about whether the fracture patterns for the two alloy products are similar or dissimilar

goes to the merits of the litigation and only underscores the potential relevance of the discovery sought here.

To the extent, Plaintiffs allege that the long neck Cobalt Chrome Device and long neck Titanium Device fractured in the same location, the Court finds the information sought in Issue No. 2 is relevant to the claims and defenses at issue in the case. (*See* Joint Stip. at 62.) Insofar as Plaintiffs seek broad discovery concerning the "short" neck Titanium Device, the Court is unconvinced that this information is relevant or proportionate to the needs of the case. Furthermore, Defendants state that in an effort to resolve this dispute, they offered to "make available to Plaintiffs . . . the *Biorn/Sarafian* production, which includes the Court-ordered production from *Biorn/Sarafian* of documents related to fracture complaints of the PHA0-1254 titanium neck component." (Joint Stip. at 65.) Defendants also note that they have already produced in these cases, "the design and regulatory files for the entire PROFEMUR® titanium neck product line[.]" (Joint Stip. at 65.) The Court finds Defendants' proposal both reasonable and comprehensive in providing adequate discovery related to the Titanium Device and such production —because it was already assembled for the *Biorn/Sarafian* Actions— imposes no undue burden on Defendants.

Accordingly, the Motion to Compel is GRANTED in part and DENIED in part as to Issue No. 2, insofar as any additional discovery concerning the PROFEMUR® Titanium neck product line will be limited to the discovery previously produced in the *Biorn/Sarafian* Actions.

Issue No. 3: Evidence of Failures in PROFEMUR® CoCr Modular Necks, Including Evidence of Corrosion

Plaintiffs seek to compel Defendants' production of documents similar to those sought in Issue No. 1 regarding the PROFEMUR® CoCr product line, but with the addition of seeking information specifically related to "evidence of corrosion" for the period 2009 through the present. (Joint Stip. at 80-83.) Plaintiffs argue that both Plaintiffs' failed devices showed evidence of corrosion, and "corrosion was part of the fretting process that led to the fractures of Plaintiffs' CoCr long neck." (Joint Stip. at 80.) During oral argument, Plaintiffs indicated that they only became aware of the potential significance of "corrosion" as a possible causative factor in the Cobalt Chrome Device fractures during expert discovery in the *Biorn/Sarafian* Actions.

Defendants, however, argue that "corrosion" and "fracture" are two different and unrelated failure modalities and for that reasons, the discovery sought here is not relevant. (Joint Stip. at 84-85.) Defendants argue that

> "fracture" is a sudden mechanical failure where the implant breaks and requires revision. On the other hand, corrosion can lead to an adverse local tissue reaction, which is a failure mode entirely separate from fracture.

(Joint Stip. at 84.) Indeed, Defendants pointed out during oral argument that separate nationwide litigation concerning adverse tissue reaction allegedly caused by PROFEMUR® hip implant products is ongoing.[4] Yet despite their strenuous arguments that corrosion and fracture are wholly separate issues, Defendants acknowledge in the same paragraph that "corrosion can lead to a fracture of the neck component, which is what allegedly happened to Plaintiffs." (*Id*.) Given this acknowledgement, Defendants' objections to the relevance of evidence in these actions concerning corrosion in the Cobalt Chrome Device are unpersuasive.

The salient question then is whether such discovery meets the proportionality requirements of Rule 26(b)(1). Defendants maintain that the design files and market surveillance files have already been produced. Defendants argue that it would be extremely burdensome to be required to review all of the individual complaint files to determine if any information on "corrosion" was noted in those files. Defendants also point out that if such broad discovery is permitted to include all component sizes of the PROFEMUR® CoCr neck product line, not just the PHAC-1254 product that was implanted in to Plaintiffs, this will add tens of thousands of additional sales of non-PHAC-1254 PROFEMUR® CoCr products into the analysis and require Defendants to review hundreds of files individually to determine whether the device failure was due to corrosion. (Joint Stip. at 87.) In light of the concrete evidence of burden that Defendants present, the Court is not persuaded that broad discovery pertaining to any corrosion-related failure is proportionate. *See McCall v. State Farm Mut. Auto Ins. Co*., Case No. 2:16-cv-01058-JAD-GWF, 2017 WL 3174914, at *6 (D. NV July 26, 2017) (noting 2015 amendments to Rule

[4] Counsel for Defendants in the nationwide adverse tissue reaction litigation, Scott Kramer, appeared telephonically at the hearing on the Motion to Compel and added some insight into the nature and scope of the adverse tissue reactions cases, which, he insisted have no overlap with the Cobalt Chrome Device fracture issues.

26(b) did not change basic rules of discovery, "although they must now be applied with a greater emphasis on proportionality").

During oral argument, Plaintiffs insisted they are entitled to information pertaining to corrosion associated with *any* type of failure of the Cobalt Chrome Device, despite the fact that the only failure modality alleged in this litigation is modular neck fracture. In an effort to support the proportionality of the discovery sought, Plaintiff pointed to Request for Production No. 40, which seeks:

> REQUEST FOR PRODUCTION NO. 40:
>
> ALL DOCUMENTS which RELATE TO COMMUNICATIONS between YOU and any implanting surgeon user discussing concerns related to corrosion and failure of the PROFEMUR DEVICE from 2000 to present.

(*See* Plaintiff's Request and Defendants' Responses, attached hereto at Appendix 3.) The Court also notes Request for Production No. 44, which is included as one of the disputed discovery requests encompassed by Issue No. 3:

> REQUEST FOR PRODUCTION NO. 44:
>
> Medical literature, papers, podium presentations, poster presentations, research, texts, treatises, or other similar DOCUMENTS, regardless of whether published or peer reviewed, received or generated by or on YOUR behalf RELATING TO the integrity, wear-rate, micromotion, corroding, fretting, or fracturing of PROFEMUR® CoCr MODULAR NECKS, regardless of the exact language used, and regardless of whether it specifically addresses a WRIGHT or MICROPORT device.

The Court finds Request Nos. 40 and 44 facially overbroad both in subject matter and temporal scope. *See Mailhoit v. Home Depo U.S.A., Inc.*, No. CV 11-03892 DOC (SSx), 2012 WL 12884129, at *2 (C.D. Cal. Sept. 4, 2012) ("Where discovery requests seek information which bears no relationship to the subject matter of the complaint, courts appropriately deny enforcement.") (internal citation omitted). Here, despite the fact that evidence of "corrosion" as a causal factor in Plaintiffs' device failure may be relevant, the only product implanted in Plaintiffs was the Cobalt Chrome Device, a long neck modular product, Catalog # PHAC-1254.

Plaintiffs fail to demonstrate that their broad requests for information, including various types of medical literature and presentations, relating to "corrosion" across the entire PROFEMUR® CoCr neck product line, and with respect to any type of failure, are proportional to the needs of this case. *See, e.g., Federal Trade Commission v. Directv, Inc.*, Case No. 15-cv-01129-HSG (MEJ), 2016 WL 3351945, at *1 (N.D. Cal. June 9, 2016) (noting court order that found party's requests "may be relevant, but they were not proportional to the needs of the case."); *Marsh v. Bloomberg Inc.*, Case No. 16-cv-02647-MEJ, 2017 WL 2224250, * 2 (N.D. Cal. May 22, 2017) ("Plaintiff fails to address how her requests are proportional to the needs of the case."). In addition, Plaintiffs fail to point the Court to a discovery request that is reasonably particularized to enable Defendants to identify potentially responsive information without undue burden.

Accordingly, to the extent the *Biorn/Sarafian* discovery may contain communications related to corrosion relating to the fracture of the PROFEMUR® Cobalt Chrome Device at issue in this case, that information will be produced. However, the Motion to Compel is DENIED as to any additional information sought in Issue No. 3.

Issue No. 4: Evidence Related to Failure Rate of the PROFEMUR® Neck Line Without Regard to Time or Specific Model

Plaintiffs also seek to compel Defendants to produce documents relating to the failure rate of the PROFEMUR® neck line of products, including titanium and CoCr necks, without limitation by time or specific product model. (Joint Stip. at 88-115.) Plaintiff argues that "[d]iscovery concerning sales and implant rates, as well as failure reports, of the PROFEMUR® neck line is necessary to allow Plaintiffs to calculate the overall fracture rate for PROFEMUR necks." (Joint Stip. at 114.) Defendants respond that they have already produced relevant responsive information in the form of detailed post-market surveillance reports for the "entire PROFEMUR® neck line product line" which, Defendants maintain, "is more than sufficient to calculate the failure for the PROFEMUR® neck line." (*Id* at 116.)

Specifically, the information already produced to Plaintiffs includes the total number of annual sales for the PROFEMUR® COCr modular neck (by year and year to date); total number of clinical incidents for the PROFEMUR® CoCr modular neck (by year and year to date); cumulative clinical incidents for the PROFEMUR® CoCr modular neck line; total number of non-clinical incidents; the cumulative non-clinical incident rate; and the total number of

reported incidents for the PROFEMUR® COCr modular neck, along with the cumulative incident rate categorized by mode of clinical failure, including fracture. (*Id*.) Plaintiffs do not dispute that this information has been provided, but argue that they should be entitled to more detailed information from individual product complaint files across the entire PROFEMUR® neck product line without regard to product number.

On this record, the Court finds that any additional discovery regarding PROFEMUR® neck products that are not as issue, including Titanium Devices and "short" neck products is neither relevant nor proportional to the needs of these cases.

Accordingly, to the extent the information sought in Issue No. 4 raises many of the same concerns regarding relevance and proportionality addressed in Issue Nos. 1-3 and additional relevant information may be contained in the *Biorn/Sarafian* discovery, the Motion to Compel is GRANTED in part, only insofar as Plaintiffs will receive the entirety of the *Biorn/Sarafian* discovery The Motion to Compel is DENIED is all other respects as to Issue Not. 4.

Issue No. 5: Communications with the FDA Regarding the PROFEMUR® Titanium Neck Line

This category of requests too strains the boundaries of relevance contemplated under Rule 26(b), particularly as Plaintiffs seeks communications for the period 2009 through January 2017 relating to the PROFEMUR® Titanium Neck Line, which was not implanted in either Plaintiff and was replaced in marketplace by the Cobalt Chrome Device in 2009.

Following oral argument on the Motion to Compel, the Court requested additional information concerning the scope of discovery sought regarding Defendants' communications with the FDA about the Titanium Device. (Dkt. No. 74.) At supplemental oral argument on Issue No. 5, Defendants indicated that some information concerning communications with the Food and Drug Administration ("FDA") about fracture incidents involving the titanium 1254 long neck product for the period 1999 – 2009 was previously produced with the *Biorn/Sarafian* discovery and, therefore, would be produced here as part of the additional discovery related to Issues 1-4, as discussed above. Plaintiffs, however, maintain that the 1999-2009 time frame is too limited and insist that Defendants should be compelled to produce documents concerning all FDA-related communications, including individual complaint files for titanium fracture incidents

from 2009 through 2017. Plaintiffs contend that documents related to titanium fracture for this extended time frame are relevant to establish "more notice" to Defendants of potential defects in the PROFEMUR® COCr Device that Plaintiffs were actually implanted with.

The Court is not persuaded that documents pertaining to titanium fracture incidents that occurred years after the Cobalt Chrome Device replaced the Titanium Device are relevant here. Accordingly, the Court concludes that the documents sought in Issue No. 5 are neither relevant to the claims and defense in this action nor proportional to the needs of the case as contemplated by Rule 26(b)(1). FED. R. CIV. P. 26(b)(1); *Marsh v. Bloomberg Inc.*, 2017 WL 2224250, at * 2.

Accordingly, the Motion is DENIED as to Issue No. 5 for documents concerning titanium fracture incidents for the period 2009 through 2017. To the extent the *Biorn/Sarafian* discovery contains relevant, responsive information concerning titanium fracture incidents for the period 1999 through 2009, that information will be produced. No additional discovery on this issue will be provided.

CONCLUSION

For the foregoing reasons, the Motion to Compel is GRANTED in part with respect to Issues 1, 2, and 4 insofar as Defendants will produce the entirety of the *Biorn/Sarafian* discovery to Plaintiffs within 10 days of the date of this Order. With respect to Issue Nos. 3 and 5, the Motion to Compel is DENIED, except to the extent relevant, responsive information may be contained in the *Biorn/Sarafian* discovery. The Motion to Compel is DENIED in all other respects.

IT IS SO ORDERED.

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